

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Vandlik et al.
 Serial No: 10/765,498
 Filed: 26 January 2004
 For: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

Group Art Unit: 3761
 Examiner: P. Bianco

Mail Stop Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE
 OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 CFR 1.97(c))**

NOTE: "An information disclosure statement shall be considered by the Office if filed ... before the mailing date of either (1) a final action under S 1.113 or (2) a notice of allowance under S 1.311, whichever occurs first, provided the statement is accompanied by either a certification as specified in paragraph (e) of this section or the fee set forth in S 1.17(p)." 37 CFR 1.97(c).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "If information submitted during the period set forth in 37 CFR 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 CFR 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

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**TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION
 DISCLOSURE STATEMENT**

- The information disclosure statement transmitted herewith is being filed AFTER THREE MONTHS OF THE FILING DATE OF THIS NATIONAL APPLICATION OR THE DATE OF ENTRY OF THE NATIONAL STAGE AS SET FORTH IN S 1.491 IN AN INTERNATIONAL APPLICATION OR AFTER THE MAILING DATE OF THE FIRST OFFICE ACTION ON THE MERITS, WHICHEVER EVENT OCCURRED LAST BUT BEFORE THE MAILING DATE OF EITHER:

- (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311,
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CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, with sufficient postage, in an envelope addressed as follows: Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on 8 December 2005

Linda S. Wenzel
 Signature of Person Signing

Linda S. Wenzel
 Type or Print Name of Person Signing

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CERTIFICATION OR FEE

2. Accompanying this transmittal is
(check either A or B below)
A. ☐ a certification as specified in 37 CFR 1.97(e)
OR
B. ☒ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under S 1.97(c). (\$180.00).

FEE PAYMENT

(complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under S 1.97(c) (\$180.00).

Fee due \$ 180.00

METHOD OF PAYMENT OF FEE

4. ☒ Attached is check in the amount of \$ 180.00
☐ Charge Account No. in the amount of \$
A duplicate of this request is attached.

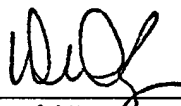
The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP 2 CON

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: 26 January 2004

Group Art Unit: 3761

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**REMARKS ACCOMPANYING
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

A Supplemental Information Disclosure Statement accompanies these Remarks.

Applicant notes that the instant application is a continuation of United States Patent Application Serial No. 09/976,833, filed October 13, 2001, now United States Patent No. 6,709,412. A copy of all pending claims 1 to 35 in the instant application is attached for the convenience of the Examiner (Tab 1).

The applicant has suggested that an interference be declared between new claims 9 to 35 of the instant application and certain claims in co-pending United States Patent Application Serial No. 10/474,805, filed April 2, 2002 (Foreign Priority: April 13, 2001), entitled "Liquid Filtering Method and Filtering System" (the '805 Application), as published as US 2004-0149657 A1 (Tab 2). Applicant believes that new method claims 9 to 17 interfere with: method claims 11 to 16 and system claims 29 to 35 of the '805 Application, as published. As indicated by PAIR, the '805 Application has been docketed to Examiner Sun U Kim in Group Art Unit 1723. As also indicated by PAIR, a Preliminary Amendment was filed in the '805 Application, amending the claims as published. A courtesy copy of the now pending claims (as amended by the Preliminary Amendment) is attached (Tab 3). Following the preliminary amendment, the interfering claims remaining in the '805 Application are believed to be method claims 11 and 12 and system claims 29 and 30.

As set forth in more detail below, applicant is aware of prior art material to the patentability of the potentially conflicting claims 9-35 in the present application and the claims of the '805 Application. Applicant is concerned that the applications be examined consistently in view of this prior art, to avoid a situation in which substantially identical claims are deemed unpatentable in one application and patentable in the other application. This prior art and these concerns regarding inconsistent examination were expressed during an interview with Examiner Bianco on November 17, 2005, as set forth in Applicant's Interview Summary filed concurrently with these Remarks..

REMARKS

The applicant directs the Examiner's attention to Krasnoff et al. United States Patent Number 5,690,815 (Krasnoff), which issued November 25, 1997. Krasnoff is of record in this case, having been listed in a previous Information Disclosure Statement. A courtesy copy of Krasnoff is attached to these Remarks (Tab 4).

The applicant also directs the Examiner's attention to Lynn et al United States Patent Number 5,591,337 (Lynn), which issued January 7, 1997. Lynn is listed in the accompanying Supplemental Information Disclosure Statement. A copy of Lynn is attached to the Supplemental Information Disclosure Statement, and a courtesy copy is also attached to these Remarks (Tab 5).

Both Krasnoff and Lynn qualify as prior art under 35 U.S.C. § 102(b) to both the present application and the '805 Application.

A. The Prior Art Krasnoff '815 Patent

Krasnoff discloses a system and method of filtering a liquid such as blood using a filter to remove, e.g., leukocytes. As expressed by Krasnoff (Col. 2, lines 42-62): "In the devices and methods of this invention, a biological fluid may be processed. For example, a biological fluid may be passed from one location to another and/or separated into one or more components or fractions. Typically, a biological fluid is passed through a porous medium ... such as a leukocyte depletion porous medium." As further expressed by Krasnoff (Col3, lines 7 to 24): "Blood Product or Biological Fluid: refers to any treated or untreated fluid associated with living organisms, particularly blood, including whole blood, warm or cold blood, and stored or fresh blood; ... one or more blood components, such as platelet concentrate (PC) , platelet-rich plasma (PRP), fresh frozen plasma (FFP), platelet- free plasma, platelet-poor plasma (PPP), plasma..."

Fig. 1 of Krasnoff shows a first container (11) holding the biological fluid, such as whole blood, which has been previously separated into a supernatant layer (31) (e.g., PRP) and a sediment layer (32) (e.g., red blood cells). As Fig. 1 shows, the first container (11) is coupled by tubing (27, 26) to first and second satellite recovery bags (41, 18). As Fig. 1 shows, the tubing (27, 26) forms a flow channel between the container (11) and each satellite bag (41, 18) contains a filter assembly (respectively 13, 17). As Fig. 1 shows, the first container (11) is placed in a differential pressure generator (51), which is located upstream of each filter assembly (13, 17). As described by Krasnoff, the differential pressure generator (51) creates a positive pressure differential between the container (11) and first and second satellite bags (41, 18). The positive pressure differential expels the layers (31 and 32) sequentially into the first and second satellite bags (41, 18) through filter assemblies (13, 17). The differential pressure generator (51) can comprise, e.g., an in-line pump. The differential pressure generator (51) can also comprise a gravity head created by mechanical, pneumatic or hydraulic means.

As expressed by Krasnoff (Col. 7, line 60 to Col 8, line 6): “Movement of the biological fluid through the system is effected by maintaining a pressure differential between the container holding the biological fluid, e.g., the collection container, and the destination of the biological fluid (e.g., a container such as a satellite bag). Exemplary means of establishing this pressure differential may be by a mechanical member such as a plate bearing directly against the collection container, an expressor such as a mechanical, pneumatic or hydraulic expressor, gravity head, applying pressure to the collection bag by hand or with a pressure cuff, by placing the other container (e.g., satellite bag) in a chamber (e.g., a vacuum chamber) which establishes a pressure differential between the collection bag and the other container, or by a pump such as an in-line pump.”

Krasnoff discloses maintaining the pressure differential by use of a control unit (50), which controls flow between the first container 11 and the satellite bags 41, 18. As expressed by Krasnoff (col. 7, lines 44 to 57): “In accordance with the present invention, processing a biological fluid through the system can be automated by coupling an automated control arrangement to the biological fluid processing assembly 10 and/or to the pressure differential generator 51. The individual parts which constitute an automated control arrangement may vary according to an intended use. In the illustrated embodiments, the automated control arrangement may comprise a control unit 50, typically a microprocessor controller, and one or more sensors, and may be coupled

to at least one of the pressure differential generator 51 and the biological fluid processing assembly 10 to control flow between the first container 11 and an-other container 41 and/or 18.”

Krasnoff discloses, in one embodiment, maintaining pressure at the outlet side of the filter at a positive pressure above atmospheric pressure (e.g., 1-3 psi) by controlling a flow rate of a feed pump (pressure differential generator) (e.g., at least 20 ml/min). As expressed by Krasnoff(Col 35, lines 31 to 57): “Sequence C (Fig. 21) serves to express the sediment PRC layer 32 from the collection bag 11 into the second satellite bag 18. In S117, a differential pressure is generated between the collection bag 11 and the second satellite bag 18 by pressurizing the pressure differential generator 51. In the expression of PRC through a leukocyte depletion assembly, it was found that a differential pressure of approximately 1-3 psi provides optimum results with respect to expression time and effectiveness of the porous medium ... In S118, valve 62 is opened and sediment PRC layer 32 in collection bag 11 is preferably passed through a leukocyte depletion assembly 17 and into the second satellite bag 18 ... The initial flow detection performs a check to verify that the flow exceeds a predetermined level, e. g., about 20 ml/minute or more. If the initial flow rate is too low ... the differential pressure may be adjusted. Once an initial flow of, for example, at least about 20 ml/minute has been detected, S120 is initiated.”

Krasnoff also discloses the filter assemblies 13 or 17 as comprising, e.g., a sheet-like filter element positioned within a suitable housing. Fig. 1 shows the housing as having an inlet port separated from an outlet port by the filter element.

As expressed by Krasnoff (Col. 3, lines 47-50): “As used herein, filter assembly refers to the porous medium positioned in a suitable housing. Suitable housings include those disclosed in U.S. Pat. Nos. 4,880,548; 4,925,572; 4,923,620; 5,100,564; 5,152,905; and U.S. Ser. No. 07/846,587.” As further expressed by Krasnoff (Col 4, lines 3-8): “The porous medium may be configured as a flat sheet, a corrugated sheet, a web, or a membrane.”

B. The Prior Art Lynn ‘377 Patent

Lynn discloses a system and method for filtering leukocytes from blood. As expressed by Lynn (Col. 3, lines 56 to 58): “A blood collection assembly 10 is shown in FIG. 1. In the illustrated embodiment, the assembly 10 serves to filter leukocytes from red blood cells before transfusion.”

Fig. 1 of Lynn shows a container (12) with tubing (14) for attachment to a conventional primary blood collection bag. The tubing (14) carries an in-line filter device 16. The filter 16

includes a two part housing 18 that encapsulates a filter pad assembly 20. The pad assembly 20 removes leukocytes from red blood cells when a gravity head is established between the primary blood collection bag and the container (12) and blood flows as a consequence from the primary blood collection bag and the container (12).

As expressed by Lynn (Col 3 line 59 to Col 4, line 23): "In the embodiment shown in FIG. 1, the assembly 10 includes a transfer bag or container 12. The transfer bag 12 includes integrally attached transfer tubing 14. In the illustrated embodiment, the tubing 14 carries a conventional blood bag spike 26 at its distal end ... The transfer tubing 14 also carries an in line filter device 16. As FIGS. 2 and 7 best show, the filter device 16 includes a two part housing 18 that encapsulates a filter pad assembly 20. The pad assembly 20 is intended to be used to remove leukocytes from red blood cells ... In use, the spike 26 is inserted into a port of a conventional primary blood collection bag (not shown). The primary bag contains red blood cells, which have been earlier separated from whole blood by centrifugation. The red blood cells flow by gravity from the primary bag into the transfer tubing 14 and through the filter device 16. The filter pad assembly 20 removes leukocytes from the red blood cells as they pass through the device 16."

Lynn discloses a filter device for removing leukocytes from blood comprising a sheet-like filter pad assembly (20) positioned within a suitable flexible housing (18). Lynn discloses the two part housing (18) as comprising two sheets of flexible plastic material. The housing has an inlet port separated from an outlet port by the filter pad assembly (20). The filter pad assembly 20 comprises sheet-like filter layers of fibrous filter media.

As expressed by Lynn (Col 5, line 1 to col. 7, line 22): " In the illustrated and preferred embodiment (best shown in FIGS. 2 and 7), the outer housing 18 enclosing the filter pad assembly 20 comprises two sheets 44 and 46 of flexible plastic material. The housing 18 is thus "soft," instead of rigid... Also in the illustrated and preferred embodiment, the filter device 16 includes tangential side ports, one port 36 (in sheet 44) serving as an inlet and the other port 38 (in sheet 46) serving as an outlet ... The ports 36 and 38 are arranged about 180 degrees apart on opposite flow sides of the filter device 16 (see FIGS. 1 and 2). This orientation facilitates the set up and use of the filter device 18 in gravity flow conditions, as FIGS. 1 and 7 show... In the illustrated and preferred embodiment (as FIG. 3 best shows), the filter pad assembly 20 comprises a composite of three media regions 28/30/32... While the constituents of the first media region 28 can vary, in the preferred

embodiment, the first media region 28 comprises a needled assembly of three non-woven polyester fiber mats... In the preferred embodiment (see FIG. 3), the second media region 30 comprises five individual layers 40 of a non-woven fiber media stacked one above the other ... In the illustrated embodiment, the third media region 32 comprises a screen of woven mesh or knitted fiber. The region 32 preferably comprises a knitted layer of polyester fibers, like a 70 denier polyester knit made by DuPont (Type 34)."

In the flexible filter shown in Lynn, the outlet side of the filter is free of a spacer, or irregularities to serve as a spacer, or a tube inserted between the outlet side of the flexible housing and the filter to serve the same purpose. The downstream layer of the filter pad assembly serves as an occlusion barrier.

As expressed by Lynn (Col 5, line 66 to Col 6, line 4): "The third media region 32 serves as a manifold. It keeps the downstream side of the filter pad assembly 20 open to fluid flow, despite the presence of a negative fluid head pressure that pulls the downstream side of the flexible housing 18 (i.e., flexible sheet 46) in against the third media region 32."

C. The Prior Art EP '678 Patent

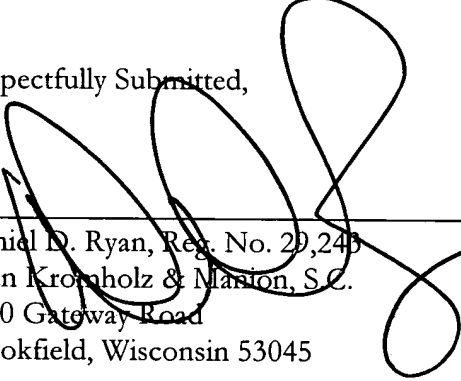
The Examiner's attention is also directed to EP 0 526 678 (listed in and attached to the accompanying Supplemental Information Disclosure Statement, with English translation) (EP 678). EP 678 was published on February 10, 1993, and also qualifies as prior art under 35 U.S.C. § 102(b) to both the present application and the '805 Application. EP 678 discloses a filter device for removing leukocytes from blood comprising a sheet-like filter pad assembly positioned within a suitable flexible housing.

D. Request for Consistent Examination

In view of the similarity between claims 9 to 35 of the present application and claims 11 to 16 and 29 to 35 of the '805 Application as published and claims 11, 12, 29, and 30 of the '805 Application pending following the Preliminary Amendment, applicant respectfully requests that the examination of these two applications be consistent. Applicant respectfully requests that the Patent and Trademark Office (PTO) and Examiners Bianco and Kim take such steps as deemed appropriate by the PTO, to avoid an inconsistent situation where substantially identical claims are deemed unpatentable in one application and patentable in the other.

Consideration of the documents listing in this and the previously considered Information Disclosure Statement and the foregoing Remarks is respectfully requested.

Respectfully Submitted,

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Pending Claims (Status)

1 (Original). A blood processing system comprising

a blood processing set including a source of blood cells, and a blood component collection flow channel coupled to the source of blood cells including a blood cell storage container and an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container, the in-line filter including a fibrous filter medium, first and second flexible housings, a unitary, continuous peripheral seal formed by application of pressure and radio-frequency heating in a single process to join the first and second flexible housings to each other, as well as join the fibrous filtration medium to the first and second flexible housings, and

a pump station adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter.

2 (Original). A blood processing system according to claim 1

further including a fixture to restrain expansion of the first and second filter housings as a result of pressure applied during operation of the pump station.

3 (Original). A blood processing system according to claim 2

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

4 (Original). A blood processing system according to claim 1

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

5 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the controller includes a function to derive a value reflecting volume of blood cells present in the blood cell storage container after passage through the filter as a percentage of volume of blood cells conveyed to the filter.

6 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the pump station includes a fluid pressure actuated pump and an actuator to apply fluid pressure to the pump.

7 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the blood cells comprise red blood cells.

8 (Original). A method of processing blood comprising using the blood processing system as defined in claim 1 or 2 or 3 or 4.

9 (Previously Presented). In a method of filtering a liquid using a filter comprising a flexible housing having an inlet port and outlet port for the liquid and a sheet-like filter element for removing undesired components from the liquid, with the inlet port being separated from the outlet port by the filter element, a method characterized by maintaining the pressure at the outlet side of the filter at a positive pressure above atmospheric pressure by controlling a feed rate per unit time of a feed pump installed in an upstream flow channel of the filter.

10 (Previously Presented). The method according to claim 9, wherein the filter does not comprise a spacer for securing a flow channel at the outlet side of the filter.

11 (Previously Presented). The method according to claim 9 or claim 10, wherein the filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet side and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

12 (Previously Presented). The method according to claim 9, wherein the liquid to be filtered is blood.

13 (Previously Presented). The method according to claim 10, wherein the liquid to be filtered is blood.

14 (Previously Presented). The method according to claim 11, wherein the liquid to be filtered is blood.

15 (Previously Presented). The method according to claim 12, wherein the filter is used for removal of leukocytes.

16 (Previously Presented). The method according to claim 13, wherein the filter is used for removal of leukocytes.

17 (Previously Presented). The method according to claim 14, wherein the filter is used for removal of leukocytes.

18 (Previously Presented). In a filtering system for a liquid comprising a filter comprising a flexible housing having an inlet port and outlet port for the liquid, a sheet-like filter element for removing undesired components from the liquid, with the liquid inlet port and the outlet port

separated from each other by the filter element, an upstream side flow channel connected to the filter inlet port, a filtered liquid recovery bag, a downstream side flow channel connecting the filter outlet port with the recovery bag, and a feed pump installed in the upstream side flow channel, a filtering system wherein the feed rate per unit time of a feed pump installed in an upstream flow channel of the filter can be controlled so that the pressure at the outlet side of the filter is maintained at positive pressure above atmospheric pressure.

19 (Previously Presented). The system according to claim 18, comprising the filter without a spacer for securing a flow channel at the outlet side of the filter.

20 (Previously Presented). The system according to a claim 18 or claim 19, wherein a filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet port and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

21 (Previously Presented). The system according to claim 18, wherein the liquid to be filtered is blood.

22 (Previously Presented). The system according to claim 19, wherein the liquid to be filtered is blood.

23 (Previously Presented). The system according to claim 20, wherein the liquid to be filtered is blood.

24 (Previously Presented). The system according to claim 21, wherein the filter is used for removal of leukocytes.

25 (Previously Presented). The system according to claim 22, wherein the filter is used for removal of leukocytes.

26 (Previously Presented). The system according to claim 23, wherein the filter is used for removal of leukocytes.

27 (Previously Presented). A liquid filtering method using the system according to claim 18.

28 (Previously Presented). A liquid filtering method using the system according to claim 19.

29 (Previously Presented). A liquid filtering method using the system according to claim 20.

30 (Previously Presented). A liquid filtering method using the system according to claim 21.

31 (Previously Presented). A liquid filtering method using the system according to claim 22.

- 32 (Previously Presented). A liquid filtering method using the system according to claim 23.
- 33 (Previously Presented). A liquid filtering method using the system according to claim 24.
- 34 (Previously Presented). A liquid filtering method using the system according to claim 25.
- 35 (Previously Presented). A liquid filtering method using the system according to claim 26.

LIST OF PRIOR ART CITED BY APPLICANT <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. 1006.F-5489 CIP 2 CON	SERIAL NO. 10/765,498
	APPLICANT Vandlik et al.	
Customer No. 26808	FILING DATE 26 January 2004	GROUP 3726



 U.S. PATENT DOCUMENTS

Examiner Initial	DOCUMENT NUMBER	Date	Name	Class	Subclass	Filing Date (If Appropriate)
	5,591,337	01/1997	Lynn et al.			
	5,690,815	11/1997	Krasnoff et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	Class	Subclass	Translation Yes No
EP 0 526 678	09/1996	EP (with English translation)			
EP 0 516 846	03/1990	EP			

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this of with next communication to applicant.